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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,833	12/27/2001	Todd A. Thompson	9345.7121-CON 4	9612

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EXAMINER	
SMITH, RUTH S	
ART UNIT	PAPER NUMBER
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/034,833	THOMPSON ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-16,18-22,51 and 60-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9-16,18-22,51 and 60-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-6,9-16,18-22,51,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al in view of Talish et al ('070). Bond et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 42 adapted to be coupled to a generator 40 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, an anticoagulant, an antiplatelet, aspirin and a fibrinolytic drug such as tPA or streptokinase. Bond et al disclose that the ultrasound applicator 42 can be the one disclosed in US Patent No. 5,879,314 to Peterson et al which is incorporated by reference. The Peterson et al

reference clearly sets forth the operating parameters as set forth in claim 1. The operating parameters are well known ultrasound therapy operating parameters for use on a patient without causing harm to the patient. Talish et al disclose an ultrasound treatment device having an assembly for positioning a transducer on the chest of a patient so that treatment can be provided without having an operator constantly hold the applicator. Talish et al disclose a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. The assembly includes a quick release mechanism as seen at the end of straps 20 in figure 1 and a quick release material as seen by the Velcro in figure 5. As seen in figure 1, the assembly can include a halter worn about the chest and shoulders. The strap assembly is substantially free of components affixed to the lateral side portion of the assembly. Assembly 22 as seen in figure 2 is for illustration purposes only. The function of the assembly is to position the transducers on the patient and to provide comfort in doing so. Talish et al fails to preclude one from making the device longer or shorter in the lateral direction. If the device were to be placed upon a very large patient, the chest of the patient, on the lateral side portions of the housing, would be substantially uncovered and bare. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. The halter assembly includes components that are worn about the back that leave the chest on opposing sides of the applicator uncovered which would allow placement of another treatment device on the chest. Talish et al disclose in column 9 that various modifications may be made in the structural configuration of the placement module. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. It would have been obvious to one skilled in the art to have modified Bond et al such that it includes the assembly of Talish et al in order to provided means for stabilize placement of the applicator on the desired area without having an operator to continuously hold such. The use of hook and loop fasteners are old and well known and it would have been obvious to one skilled in the art to have replaced the clips with hook and loop fasteners.

Such a modification merely involves the substitution of one well-known type of quick release mechanism for another. With regard to claims 5-6, the specific arrangement of the assembly used would have been an obvious design choice of known equivalents for providing placement of the transducer on the desired location in view of the Tallish et al disclosure referred to above. With regard to claims 15,16, Talish et al disclose means to releasably couple to transducer assembly to the electric generating means/battery. It would have been obvious to one skilled in the art to have further modified Bond et al such that it includes means to releasably couple to transducer assembly to the electric generating means in order to be able to easily change the battery if necessary.

Claims 60-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al in view of Talish et al as applied to claim 1 above, and further in view of Barsotti et al. Bond et al fails to specifically disclose the use of either or both continuous or pulsed wave ultrasound. Barsotti et al disclose that ultrasound therapy can be provided in either continuous wave mode or pulsed wave mode. Barsotti et al further disclose that various operating modes can be selected and varied depending upon the treatment desired. The modes can comprise different output power levels and are either pulsed or continuous wave ultrasound. In the absence of any showing of unexpected results the specific operating parameters selected would have been an obvious design choice without undue experimentation for achieving the desired effect. Therefore, it would have been obvious to one skilled in the art to have further modified Bond et al to includes means for varying the operating parameters as disclosed by Barsotti in order to allow one to change the conditions of the treatment provided.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al in view of Talish et al as applied to claim 1 above, and further in view of Moehring et al and Berger et al. Moehring et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 128 adapted to be coupled to a generator 134 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, and a fibrinolytic drug such as tPA or streptokinase. Moehring et al disclose providing an image of the treatment site in order to properly locate the site

prior to treatment. Berger et al disclose imaging of thrombi before treatment and the use of an EKG device to aid in triggering the image device. The use of an EKG trigger in an imaging system is old and well known means to eliminate motion artifacts. Therefore, it would have been obvious to one skilled in the art to have further modified Bond et al to include means for imaging the treatment site prior to treatment and an EKG device as a source of a trigger signal in order to properly locate the treatment site prior to treatment and eliminate motion induced artifacts from the image.

Claims 1,3-6,9-16,18,21,51,60-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring et al in view of Talish et al ('070). Moehring et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 128 adapted to be coupled to a generator 134 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, and a fibrinolytic drug such as tPA or streptokinase. Moehring et al sets forth the operating parameters as set forth in claim 1. For example, Moehring et al discloses a power density of 50mWatts/cm^2, a power output of a few milliwatts to a few watts (column 5) and a therapeutic frequency of 200KHz. The operating parameters are well known ultrasound therapy operating parameters for use on a patient without causing harm to the patient. Talish et al disclose an ultrasound treatment device having an assembly for positioning a transducer on the chest of a patient so that treatment can be provided without having an operator constantly hold the applicator. Talish et al disclose a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. The assembly includes a quick release mechanism as seen at the end of straps 20 in figure 1 and a quick release material as seen by the Velcro in figure 5. As seen in figure 1, the assembly can include a halter worn about the chest and shoulders. The strap assembly is substantially free of components affixed to the lateral side portion of the assembly. Assembly 22 as seen in figure 2 is for illustration purposes only. The function of the assembly is to position the transducers on the patient and to provide comfort in doing so. Talish et al fails to preclude one from making the device longer or shorter in the lateral direction. If the device were to be

placed upon a very large patient, the chest of the patient, on the lateral side portions of the housing, would be substantially uncovered and bare. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. The halter assembly includes components that are worn about the back that leave the chest on opposing sides of the applicator uncovered which would allow placement of another treatment device on the chest. Talish et al disclose in column 9 that various modifications may be made in the structural configuration of the placement module. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. It would have been obvious to one skilled in the art to have modified Moehring et al such that it includes the assembly of Talish et al in order to provided means for stabilize placement of the applicator on the desired area without having an operator to continuously hold such. The use of hook and loop fasteners are old and well known and it would have been obvious to one skilled in the art to have replaced the clips with hook and loop fasteners. Such a modification merely involves the substitution of one well-known type of quick release mechanism for another. With regard to claims 5-6, the specific arrangement of the assembly used would have been an obvious design choice of known equivalents for providing placement of the transducer on the desired location in view of the Talish et al disclosure referred to above. With regard to claims 15,16, Talish et al disclose means to releasably couple to transducer assembly to the electric generating means/battery. It would have been obvious to one skilled in the art to have further modified Moehring et al such that it includes means to releasably couple to transducer assembly to the electric generating means in order to be able to easily change the battery if necessary. With respect to claims 60-67, Moehring et al disclose that the ultrasound therapy can be provided in either continuous wave mode or pulsed wave mode. The modes can comprise either pulsed or continuous wave ultrasound. In the absence of any showing of unexpected results the specific operating parameters selected would have been an obvious design choice without undue experimentation for achieving the desired effect.

Claims 19,20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring et al in view of Talish et al as applied to claim 1 above, and further in view of Bond et al. Bond et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 42 adapted to be coupled to a generator 40 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, an anticoagulant, an antiplatelet, aspirin and a fibrinolytic drug such as tPA or streptokinase. It would have been obvious to one skilled in the art to have further modified Moehring et al such that the agent is an anticoagulant, an antiplatelet, and aspirin. Such a modification merely involves the substitution of one type of agent used to promote dissolution of thrombi for another.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring et al in view of Talish et al as applied to claim 1 above, and further in view of Berger et al. Moehring et al disclose providing an image of the treatment site in order to properly locate the site prior to treatment. Berger et al disclose imaging of thrombi before treatment and the use of an EKG device to aid in triggering the image device. The use of an EKG trigger in an imaging system is old and well known means to eliminate motion artifacts. Therefore, it would have been obvious to one skilled in the art to have further modified Moehring et al to include an EKG device as a source of a trigger signal in order to properly locate the treatment site prior to treatment and eliminate motion induced artifacts from the image.

Response to Arguments

Applicant's arguments filed January 16, 2007 have been fully considered but they are not persuasive. With respect to the comments regarding the device of Talish et al not leaving the chest on the sides of the housing bare, assembly 22 as seen in figure 2 is for illustration purposes only. The function of the assembly is to position the transducers on the patient and to provide comfort in doing so. Talish et al fails to preclude one from making the device longer or shorter in the lateral direction. Furthermore, Talish et al disclose, in column 9, that various modifications can be made to the structural configuration of the placement module. Such modifications would have

been an obvious design choice based upon many factors such as where the module is positioned and whether other testing is to be performed simultaneously therewith. The modifications do not require that the placement assembly be custom fit to a patient such that it extends completely across the patient's chest.

It should be noted that the status identifier for claim 69 is incorrect. It should have set forth that the claim was "previously presented".

Conclusion

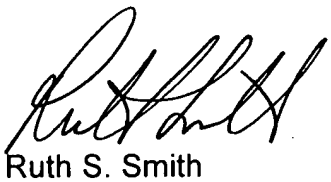
All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS